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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 9933 09/955,933 09/20/2001 Luba Cohen 2786-0191P **EXAMINER** 06/14/2006 7590 BIRCH, STEWART, KOLASCH & BIRCH, LLP WARE, DEBORAH K P.O. Box 747 ART UNIT PAPER NUMBER Falls Church, VA 22040-0747 1651

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No.		Applicant(s)		
		09/955,933		COHEN, LUBA		
		Examiner		Art Unit		
		Deborah K. War	e	1651		
The MAILING DATE of this co Period for Reply	ommunication appe	ears on the cove	r sheet with the c	orrespondence ad	ldress	
A SHORTENED STATUTORY PER WHICHEVER IS LONGER, FROM  - Extensions of time may be available under the patter SIX (6) MONTHS from the mailing date of If NO period for reply is specified above, the ma Failure to reply within the set or extended period Any reply received by the Office later than three earned patent term adjustment. See 37 CFR 1.	THE MAILING DA provisions of 37 CFR 1.136 this communication. ximum statutory period will for reply will, by statute, or months after the mailing of the statute.	TE OF THIS CO 6(a). In no event, how Il apply and will expire cause the application	OMMUNICATION rever, may a reply be times SIX (6) MONTHS from to become ABANDONED	l. ely filed the mailing date of this c O (35 U.S.C. § 133).		
Status						
1) Responsive to communication	n(s) filed on <i>27 Jur</i>	ne 2005.				
2a) ☐ This action is <b>FINAL</b> .		action is non-fir	al.			
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closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	<b>F</b>	, ,	,		,	
·	n the englication					
<ul> <li>4)⊠ Claim(s) 1-22 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> </ul>						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-22</u> is/are rejected. 7)□ Claim(s) is/are objected to.						
7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.						
· · · · · · · · · · · · · · · · · · ·	restriction and/or	election require	ancii.			
Application Papers			·			
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
See the attached detailed Office action for a list of the certified copies flot received.						
	ıs					
Attachment(s)						
1) Notice of References Cited (PTO-892)		4) 🗀	Interview Summary (	(PTO-413)		
2) Notice of Draftsperson's Patent Drawing R		Paper No(s)/Mail Da	te	O 453)		
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:						

#### **DETAILED ACTION**

Claims 1-22 are presented for examination on the merits.

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2005, has been entered.

### Response to Amendment

The amendment filed June 27, 2005 has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Claim Rejections - 35 USC § 102

Claims 1-5, 7, 10-11, 13, 16-17, 19 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fuhrman et al, cited of record.

### Response to Arguments

Applicant's arguments filed June 27, 2005, have been fully considered but they are not persuasive. However, successful results were obtained for using the garlic as an antioxidant to lower total blood cholesterol and LDL levels. These are at least two risk factors. Fuhrman et al clearly teach that licorice extract resulted in reduction in

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LDL susceptiability, note abstract, last eight lines of the abstract. This lowering of susceptibility of LDL inherently includes LDL susceptibility to aggregation and retention which are at least two of the risk factors as well. Also the lowering of total blood cholesterol and LDL levels are also considered to be anticipated by the teachings of the cited reference, Fuhrman et al. The lowering of the risk factors as claimed would be the result of administering the licorice extract of Fuhrman et al to a patient. Also the patient of the claims is not even required to be suffering from a risk factor or be susceptible to a risk factor. Fuhrman et al is the documentary evidence along with Applicant's second noted document of record which teaches that antioxidants lower risk factors. Therefore, the examiner submits that a valid prima facie case of anticipation has been set forth as discussed above and of record. Thus, the rejection is maintained.

## Claim Rejections - 35 USC § 103

Claims 6, 8, 12, 14, 18, and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrman et al, cited of record and above as well, for those reasons of record.

#### Response to Arguments

Applicant's arguments filed June 27, 2005, have been fully considered but they are not persuasive. It is noted that Applicant asserts that Fuhrman et al teach away from the present claimed invention. However, the study referred to be Applicant was only carried out for two weeks, and although no significant change could be found in the LDL-cholesterol and in certain other characteristics such as blood count, coagulation tests, or renal or liver function tests, it should be noted that this study was conducted on

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young healthy humans so the rate of lipid peroxidation was most likely normal which may explain why no changes were observed. However, in the study on the atherosclerotic mouse successful results were observed because of increased lipid peroxidation.

Note page 273, first and columns, all lines. Note that the lesion is significantly smaller in B of Figure 7, this is the patient receiving the licorice extract. This extract also does not contain glycyrrhizinic acid, note at page 268, at "METHODS" section, subsection "Materials" at lines 6-7 the term "licorice" in Fuhrman et al is referring to a licorice extract free of glycyrrhinic acid. Therefore, once again the alleged teaching away of Fuhrman et al is not deemed persuasive. The cited reference clearly sets forth a prima facie case of obviousness and is not at all directed to an "obvious to try" type of teaching. Thus, the rejection is maintained because an obvious to try standard has not been applied.

Claims 9, 15 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrman et al in view of the admitted prior art (see specification at page 1, lines 10-12) for reasons set forth of record.

### Response to Arguments

Applicant's arguments filed June 27, 2005, have been fully considered but they are not persuasive. The argument that hypertension is not disclosed and that Fuhrman et al even in view of admitted prior art does not suggest or disclose treating this condition is noted.

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However, the cited Fuhrman et al reference clearly does teach the administering of an amount of licorice extract which is demonstrated to be effective by Fuhrman for reduction of susceptibility of LDL to oxidation of which has been implicated in cardiovascular disease.

Hypertension has also been implicated in cardiovascular disease. Also the prior art has recognized glycyrrhizinic acid to be causative of hypertension. Further, it is maintained that Fuhrman et al teach a glycyrrhizinic acid free licorice extract, therefore, to treat hypertension would have been prima facie obvious. Thus, the rejection is maintained.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8200.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware June 10, 2006 PATENT EXAMINER